§ 60.32 Applicant response to petition.

(a) The applicant shall file with FDA a written response to the petition no later than 30 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent extension application.

(c) If the applicant does not respond to the petition, FDA will decide the matter on the basis of the information submitted in the patent term restoration application, due diligence petition, and FDA records.

§ 60.34 FDA action on petitions.

(a) Within 90 days after FDA receives a petition filed under § 60.30(a), the agency will either deny the petition under paragraph (b) or (c) of this section or investigate and determine under § 60.36 whether the applicant acted with due diligence during the regulatory review period. FDA will publish its due diligence determination in the FEDERAL REGISTER, notify PTO of the due diligence determination in writing, and send copies of the notice to PTO, the applicant, and the petitioner.

(b) FDA may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 60.30;

(2) The petition is not filed in accordance with § 10.20;

(3) The petition does not contain the information required by § 10.30;

(4) The petition fails to contain information or allegations upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period; or

(5) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition would not affect the maximum patent extension the applicant sought in the application.

§ 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. FDA will take into consideration all relevant factors, such as the amount of time between the approval of an investigational exemption or research permit and the commencement of a clinical investigation and the amount of time required to conduct a clinical investigation.

(b) For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearings

§ 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Dockets Management Branch and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered